REMARKS

The Claimed Invention

The claimed invention is directed to amphetamine derivatives and anitbodies against them.

The Pending Claims

Prior to entry of the above amendments, Claims 1-51 are pending.

The Office Action

Claims 7,8 and 10-14 are allowed

Claims 1-4, 9 and 15-51 stand rejected under 35 U.S.C. 102(b) as being anticipated by JP 05005737 published 06/28/1991.

Claim 5 stands rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,976,812, published 02 November 1999.

Claim 6 stands rejected under 35 U.S.C. 102(b) as being anticipated by U.S.Patent 4,041,076, published 09 August 1977.

Amendments

Support for the amendment to either the S enantiomer or the R enantiomer is found throughout the specification and in Claims 2 through 8 and 42.

Response to the objections and rejections

In the response that follows, the Examiner's individual rejections are provided in full text, as identified by indented small bold print, followed by Applicant's response.

35 U.S.C. 102(b) Rejections

Claims 1-4, 9, and 15-51 are rejected under 35 U.S.C. 102 (b) as being anticipated by JP 05005737 published 06/28/1991 (computer generated English translation enclosed).

1. Claims 1- 4

This rejection is respectfully traversed in regard to Claim 1, and avoided in regard to Claims 2 and 4 by amendment of the claims to recite that the compound is either the S or the R enantiomer. The cited Japanese patent discloses a single compound that comes within formulas I (Claim 1), II (Claim 2) and VII (Claim 4), namely a compound wherein R2=CH2COOH (Japanese formula 2), but the reference teaches only how to make a racemic mixture of the compound, not the claimed S-enantiomer (Claim 1) or the individual enantiomers (Claims 2 and 4). Not only is the stereochemistry different, but it is well known that the biological effects of the S and R enantiomers are different both from each other and from racemic mixtures of a given compound. Disclosure of the racemic mixture does not anticipate the enantiomers. The formula disclosed in JP 05005737 does not come within Formula VI (Claim 3) and therefore does not anticipate this Claim. Accordingly, the Examiner is respectfully requested to withdraw the rejection as to Claims 1- 4.

2. Claim 9

This rejection is respectfully traversed because the claimed method for preparing a compound of formula VII is not taught by the cited reference. Accordingly, the Examiner is respectfully requested to withdraw this rejection of Claim 9.

3. Claims 15-20 and 41

This rejection is respectfully traversed as to Claims 17 and 18 because the cited Japanese patent does not teach compounds having formula IIIa or formula IIb, the compound that is coupled to the carrier. This rejection is avoided by amendment of Claims 15 and 16 to recite that compound is an (S) enantiomer or an (R) enantiomer. Claim 19 depends from Claims 15-18 and since these claims are patentable over the cited reference, Claim 19 is patentable. As to Claim 20, this rejection is respectfully traversed

because there is no disclosure relating to tetanus toxoid toxin in the cited Japanese patent. The only carriers that are disclosed that are coupled to the N-carboxymethyl methamphetamine are bovine serum albumin and keyhole limpet hemocyanin. As to Claim 21, since Claim 15 is patentable over the Japanese patent, Claim 21 is patentable. As to Claim 22, since Claims 18 and 20 are patentable over the Japanese patent, Claim 22 is patentable. Since Claim 22 is patentable, a method of using the vaccine according to Claim 22 also is patentable. Accordingly, the Examiner is respectfully requested to withdraw this rejection of Claims 15-22 and 41.

4. Claims 23-27.

This rejection as been avoided by amendment of Claim 23, from which the remaining claims ultimately depend, to recite that the amphetamine or derivative of amphetamine is an (S) enantiomer or an (R) enantiomer. Accordingly, the Examiner is respectfully requested to withdraw this rejection of Claims 23-27.

5. Claims 28-40.

This rejection is respectfully traversed because the only hybridoma that is disclosed in the cited Japanese patent was prepared using as immunogen MA-AB-BSA-GA; the amphetamine is racemic N-(4-amino butyl) methamphetamine. The antibody produced by the hybridoma is disclosed as binding to a single amphetamine, methamphetamine. The claimed antibodies bind to at least two amphetamines (see Table IV). The claimed cell lines and hybridomas produce monoclonal antibodies that bind to at least two amphetamines. The claimed immunoglobulin fragments bind to at least two amphetamines and the claimed pharmaceutical composition comprises antibodies that bind to at least two amphetamines. Since the compositions are patentable over the cited Japanese patent, methods of using the patentable material also are patentable. Accordingly, the Examiner is respectfully requested to withdraw this rejection as to Claims 28-40.

6. Claim 42.

This rejection is respectfully traversed because there is no teaching in the cited Japanese patent regarding the S-enantiomer. Accordingly, the Examiner is respectfully requested to withdraw this rejection of Claim 42.

7. Claims 43-50.

This rejection is respectfully traversed because there is no disclosure in the cited Japanese patent relating to isolated nucleic acids, expression vectors, or host cells. Accordingly, the Examiner is respectfully requested to withdraw this rejection of Claims 43-50.

8. Claim 51.

This rejection is respectfully traversed because the cited Japanese patent does not disclose a method for making an immunoglobulin specific for at least two amphetamines or amphetamine derivatives. Accordingly the Examiner is respectfully requested to withdraw this rejection of Claim 51.

Claim 5 is rejected under 35 U.S.C. 102 (b) as being anticipated by U.S. Patent 5,976,812, published 02 November 1999. See figure 1, structure 5, or figure 2, structure 14.

This rejection has been avoided by amendment of Claim 5 to recite that R11 is either a polymethylene chain: $-(CH_2)_m-$, wherein m is an integer between 1 and 3 or an oxy-polymethylene chain: $-O(CH_2)_o-$, wherein o is an integer between 1 and 4. There is no disclosure relating to such compounds in the cited reference. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S.Patent 4,041,076, published 09 August 1977. See column 1, lines 55 to column 2 lines 1-4.

This rejection is respectfully traversed because the claimed compound is not taught by the

cited reference. In the compound of Claim 6, using the same side group designations as the cited reference, R1=H, R2=H, R3=CH3, R4=H, R4'=CH3, R5=H, and n=1. In the compound of formula II, R3=H and R4' is H or an amine protecting group, preferably a t-butoxycarbonyl group to prevent serf-condensation reactions during further transformations in the preparation of needed antigens (see USPN 4,041,076 column 2, lines 1-9). The disclosure therefore teaches away from the use of a methyl group at the R4' position. The Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

In view of the above amendment and remarks, it is submitted that this application is now ready for allowance. Early notice to that effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney at (831) 648-3090 Ext 103.

Respectfully submitted,

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